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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,563

04/16/2004

Mark A. Hoffman

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SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108-2613

EXAMINER

SIMS, JASON M

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,563

Applicant(s)

HOFFMAN ET AL.

Examiner

Jason M. Sims

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-8,10,12-15,17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-8,10,12-15,17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Applicant's arguments, filed 7/25/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 7/25/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant's cancellation of claims 2, 4, 9, 11, 16, and 18 in the response filed 7/25/2007 is acknowledged.

Claims 1, 3, 5-8, 10, 12-15, 17, and 19-21 are the current claims hereby under examination.

Drawings

The objection to the drawings has been withdrawn because of applicant's submission of new drawings.

The drawings received on 7/25/2007 have been accepted and entered.

Claim Rejections - 35 USC § 101

Response to Arguments:

Applicant's arguments, filed 7/25/2007, with respect to the rejection of claims under 35 USC 101 as being drawn to non-statutory subject matter have been fully considered and are persuasive because of applicant's amendment. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112 1st Paragraph

Response to Arguments:

Applicant's arguments, filed 7/25/2007, with respect to the rejection of claims under 35 USC 112 first paragraph as lacking enablement have been fully considered and are persuasive because of applicant's arguments and amendments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention.

The following rejection has been maintained:

Claims 1, 8, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. While it is appreciated that applicants have amended their claims to attempt to overcome the prior rejection of missing elements in said claims, there are still apparent missing elements.

The omitted elements are: a recited relationship between the output information regarding the likelihood that a person has a gene variant indicative of an atypical

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event based on hereditary information and preventing the atypical clinical event, as recited in the preamble. There is no connection between the output information (i.e. the recited method steps) and preventing an atypical event (i.e. the intended result recited in the preamble), therefore the connection between the various claim elements is unclear, and the claims are indefinite.

Claims 2-7, 9-14, and 16-20 are rejected as being dependent from a rejected claim.

Response to arguments:

Applicant's arguments filed 7/25/2007 with respect to the rejection of claims 1, 8, and 15 for missing essential elements have been fully considered but they are not persuasive.

Applicant alleges that the amendment to claims overcomes this rejection. Applicant's allegations are not found persuasive as there are still missing essential elements between the output information regarding the likelihood that a person has a gene variant indicative of an atypical event based on hereditary information and preventing the atypical clinical event. Therefore the rejection that claims 1, 8, and 15 are missing essential elements is being maintained as stated above.

Applicant's arguments, filed 7/25/2007, with respect to the other rejections of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's cancellation of claims and amendments to the claims. Therefore the rejections have been withdrawn.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

Marjorie A. Moran
SPE, AU 1631
10/1/07